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Mortality of ruptured abdominal aortic aneurysm treated with open or endovascular repair

Eric L. Verhoeven, MD, PhD,^a Marten R. Kapma, MD,^b Henk Groen, PhD,^c Ignace F. Tiellu, MD,^a Clark J. Zeebregts, MD, PhD,^a Foppe Bekkema, RN, MANP,^a and Jan J. van den Dungen, MD, PhD,^a *Groningen and Amsterdam, The Netherlands*

Objectives: The study defined the selection criteria used for treatment of ruptured abdominal aortic aneurysms (RAAAs) and reviewed results during a 5-year period.

Methods: From 2002 on, our tertiary referral center adopted a protocol of selective use of endovascular repair for RAAAs. The study included all patients with a proven RAAA who were admitted to our hospital from 2002 to 2006. The primary outcome measure was surgical mortality.

Results: A total of 187 patients were admitted with an acute AAA, and an RAAA was confirmed 135 (72%) by computed tomography scanning or at laparotomy, and 125 (93%) were treated, 89 by open means and 36 by endovascular means. The overall mortality rate was 24% and the mortality rate was 13.9% for endovascular repair. Endovascular repair was consistently used more often in patients with favorable anatomy and in patients who were hemodynamically more stable. There were considerable differences in approach between the four consultant vascular surgeons. The overall evaluation and inclusion for endovascular treatment increased during the study period.

Conclusions: A strict protocol for admission, evaluation, and treatment of RAAA, with selective use of endovascular repair, resulted in low mortality rates in our center. (*J Vasc Surg* 2008;48:1396-1400.)

A meta-analysis of open repair of ruptured aortic abdominal aneurysms (RAAAs) demonstrated a 30-day mortality of 48%, with a constant reduction of only approximately 3.5% per decade (1954 to 1997) and with an estimated 41% operative mortality rate for the year 2000.¹ Since it was first used in 1994, endovascular repair (EVAR) of RAAA has emerged as a promising alternative treatment to open surgical repair.²⁻⁹ Two systematic reviews confirmed the potential benefits of EVAR for RAAAs.^{10,11} A randomized controlled trial, which was terminated before achieving the appropriate sample size due to poor enrollment and use of inclusion criteria that are not generalizable to many centers using endovascular repair for RAAA, showed a 30-day mortality of 53% in both the open repair and EVAR arm.¹²

The interpretation of current results from the literature is difficult because of patient selection criteria, definition of anatomic suitability for EVAR, and definition of hemodynamic stability. In addition, as shown by the Albany group,¹³ a standardized protocol for EVAR of RAAA needs to be established. These factors are probably limiting the

use of EVAR in RAAA, and many centers are still offering only open repair.

In 2002 we adopted a protocol of selective use of EVAR for RAAA, and encouraged by the results, we have continued to offer both treatment modalities.¹⁴ The purpose of this study was to define the selection criteria that we used for each treatment modality and to review results during a 5-year period.

PATIENTS AND METHODS

This study was conducted in a tertiary vascular center with expertise in EVAR as defined by Forbes et al¹⁵ and after a preceding feasibility trial of which the results have been reported elsewhere.¹⁴

Study design. As of January 1, 2002, all patients with an acute RAAA were recorded, and those entered between 2002 and 2006 were included in this study. An aneurysm was defined as ruptured when blood was identified outside the aorta on computed tomography (CT) scanning or as a retroperitoneal hematoma found at laparotomy. All other AAA patients, including those with an acute, nonruptured AAA, were excluded.

Our management protocol for acute AAA has been described before.^{6,14} In brief, evaluation of each patient was done simultaneously by the on-call vascular surgeon, the anesthetist, and an interventional radiologist. Whenever possible, a CT scan was immediately ordered to confirm the diagnosis and to evaluate suitability for EVAR. Intravenous fluid infusion was minimized, and hypotension was accepted as long as the patient remained conscious with coherent verbal responses. The decision to order a CT scan was left to the on-call team rather than defining a lowest blood pressure threshold.

From the Departments of Surgery^a and Epidemiology,^c University Medical Center Groningen, Groningen; and the Department of Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam.^b

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Correspondence: Eric L. G. Verhoeven, MD, PhD, Department of Surgery, Division of Vascular Surgery, University Medical Center Groningen, Hanzeplein 1, PO Box 30,001, 9700 RB Groningen, The Netherlands (e-mail: e.l.g.verhoeven@chir.umcg.nl).

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Whenever the multidisciplinary on-call team made the decision not to evaluate the patient for EVAR because of hemodynamic instability, open treatment was initiated without further delay. Anatomic suitability for EVAR was evaluated according to guidelines for elective EVAR, including proximal neck length >1.5 cm with $<60^\circ$ angulation and access vessels large enough (7 mm) to accommodate the introducer systems. However, in selected cases, a neck length between 5 and 15 mm was also considered for EVAR.

Local anesthesia was the preferred choice for EVAR, with additional intravenous sedation and analgesia if required. General anesthesia was used only if patient cooperation proved insufficient or in combination with an aortouniiliac (AUI) device, followed by a crossover bypass. In that case the procedure was started under local anesthesia and converted to general anesthesia after insertion of the AUI.

The preferred endovascular graft configuration was a bifurcated prosthesis. AUI configuration was used only if a bifurcated device was contraindicated due to insufficient bilateral access. The surgical technique of EVAR, as well as the use of local anesthesia, is described elsewhere in detail.¹⁴

Outcome measures. The primary clinical outcome was mortality (30-day mortality and hospital mortality). Secondary outcomes were duration of procedure, intensive care unit and hospital length of stay, transfusion requirements, early and late complications, reinterventions, and long-term survival.

Statistical analysis. Data were prospectively entered in a database, and analyses were conducted using SPSS 15.1 software (SPSS Inc, Chicago Ill). Variables were expressed as median \pm standard deviation. The *t* test and Mann-Whitney *U* test were used for comparison of continuous variables with normal and skewed distributions, respectively. The Pearson χ^2 test was used for categorical variables, and the Kruskal-Wallis test was used for more than two variables. Survival was analyzed using Kaplan-Meier curves and log-rank testing. Differences were considered statistically significant with a value of $P < .05$.

RESULTS

Patient admission. During a 5-year period, 187 patients were admitted with an acute AAA; of these, 52 were excluded (49 had a nonruptured acute AAA, 2 had an aortoduodenal fistula, and 1 had a suprarenal mycotic aneurysm), leaving 135 patients with a RAAA. Their median age was 72 ± 8.7 years, and 116 (86%) were men. General practitioners had referred 99 patients (73%) directly through ambulance services. No patient who was announced by ambulance services died during transport. Another 32 patients (24%) were referred from other hospitals, 23 because no intensive care unit was available and nine because the local hospital lacked surgical expertise at that moment. Four patients were internal referrals (2 from the dialysis unit, 1 from the coronary care unit, and 1 from the recovery unit after a laparotomy).

At the time of admission, 77 patients (group I) were regarded stable with a systolic blood pressure of >100 mm Hg, 24 patients (group II) had a systolic blood pressure between 70 and 100 mm Hg, and the remaining 34 patients (group III) had a systolic blood pressure of <70 mm Hg.

Evaluation and treatment. Evaluation for EVAR occurred in 104 patients (77%). No evaluation was done in 31 patients, including four who received no treatment. Three patients were not treated because of advanced age and comorbidity, and one patient died shortly after arrival. In the remaining 27 patients, 23 were not evaluated because of hemodynamic instability in 21 or unrest due to pain in 2 (1 group I, 2 group II, 20 group III). Three patients were not evaluated for logistic reasons: no endovascular team was available ($n = 2$) and a second endovascular procedure was not possible ($n = 1$). The reasons one patient was not evaluated are unknown.

Treatment was initiated in 125 patients (93%), and 10 patients were not treated, including six who were evaluated but were not suitable for EVAR. Open treatment was done in 89 patients (71%), and 36 (29%) had EVAR. Open treatment was done in 27 patients who were not evaluated for EVAR as mentioned and in 62 patients who underwent a CT scan. Of these 62 patients, 26 were unsuitable for EVAR due to an overly short proximal neck, 16 due to an aortoiliac aneurysm to both iliac bifurcations, 7 due to insufficient access, and 13 due to a combination of previous reasons. Open treatment was initiated significantly more in hemodynamically unstable patients ($P = .001$, Fig 1). In 31 of 89 patients (35%) who had open repair, suprarenal clamping was necessary but no renal artery reconstruction was performed.

Evaluation for EVAR increased from 62.5% in the first year to 80% and more in the last 3 years of the study. The percentage of patients treated by EVAR increased gradually, from 18% to 37.5%, during the 5-year study period (Fig 2). There was a significant difference in patient selection for EVAR by the surgeon who was on-call, varying from 45% to 8% (Fig 3, $P < .001$).

The time to the start of the procedure was significantly shorter in the patient group treated by open means without CT scanning (median 26 ± 20 minutes) vs EVAR and CT scanning (median 45 ± 24 min) and open repair plus CT scanning (median 45 ± 33 minutes; $P < .001$).

Of the 36 EVAR procedures, 30 (83%) were performed under local anesthesia only. Three additional procedures were started under local anesthesia but required general anesthesia afterwards, two to evacuate hematoma causing an abdominal compartment syndrome, and one because of asystolia. Two patients were initially treated under general anesthesia because of unrest, and one stable obese patient was treated under epidural anesthesia.

Device distribution was 31 Zenith Tri-Fab devices and one Zenith AUI system (Cook Inc, Bloomington, Ind); three Excluder devices (W. L. Gore and Associates, Flagstaff, Ariz); and one patient was treated with a Zenith Tri-Fab body in conjunction with Excluder limbs.

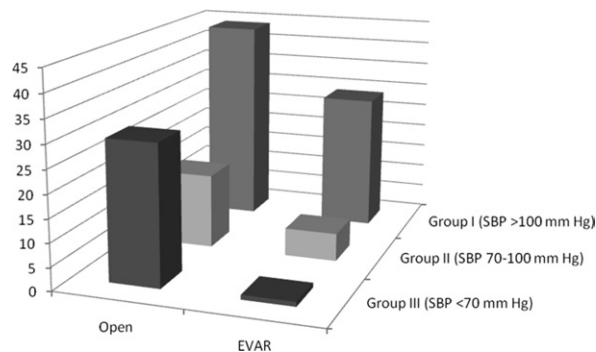


Fig 1. Number of patients with ruptured abdominal aortic aneurysm treated by open means and by endovascular repair (EVAR) according to hemodynamic stability at arrival in emergency department. SBP, Systolic blood pressure.

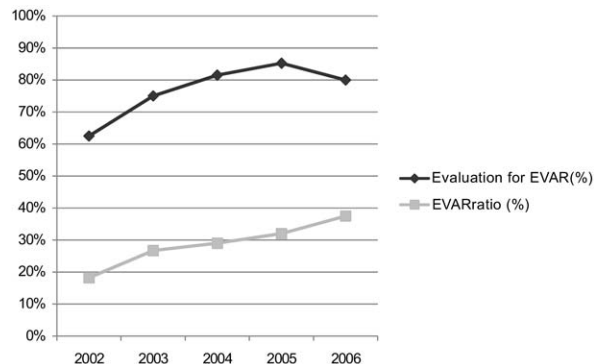


Fig 2. Percentage of patients evaluated for endovascular aneurysm repair (EVAR, diamonds) and treated by EVAR (squares) during the study period.

Operation time was significantly lower with EVAR than with open repair (median 85 ± 27 vs 200 ± 62 minutes, $P < .001$). Transfusion requirement of packed cells (median 0 ± 4 vs 5 ± 6 U), intensive care unit stay (median 0 ± 85 vs 72 ± 246 hours), and hospital stay (median 5 ± 10 vs 20 ± 20 days) were all in favor of EVAR ($P < .001$ for each factor).

Mortality. Overall mortality by intention-to-treat was 27% (36 of 131), with only four patients (3%) denied treatment. This includes the six patients who were evaluated for EVAR but were unsuitable and denied open treatment due to age and comorbidity.

Mortality as per on-treatment, with 93% of all RAAA treated, was 24% (30 of 125), with an open mortality of 28.1% (25 of 89) and EVAR mortality of 13.9% (5 of 6; $P = .092$).

Mortality according to hemodynamic stability and treatment modality is compiled in the Table, with the highest mortality in group III. (Kruskal-Wallis test: $P = 0.193$ for open repair, $P = 0.042$ for EVAR, $P = .051$ for total group.)

Mortality per surgeon was not statistically different for the four attending vascular surgeons (excluded were the

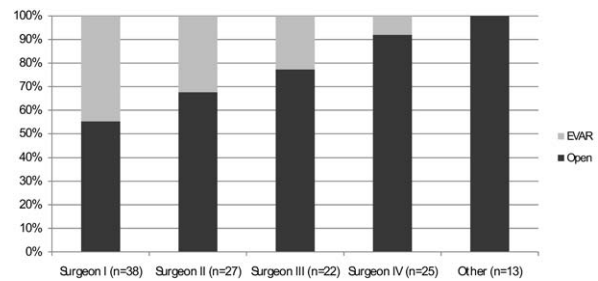


Fig 3. Selection for endovascular aneurysm repair (EVAR, gray bars) and open repair (black bars) by individual vascular surgeon, with total number of treated patients between brackets.

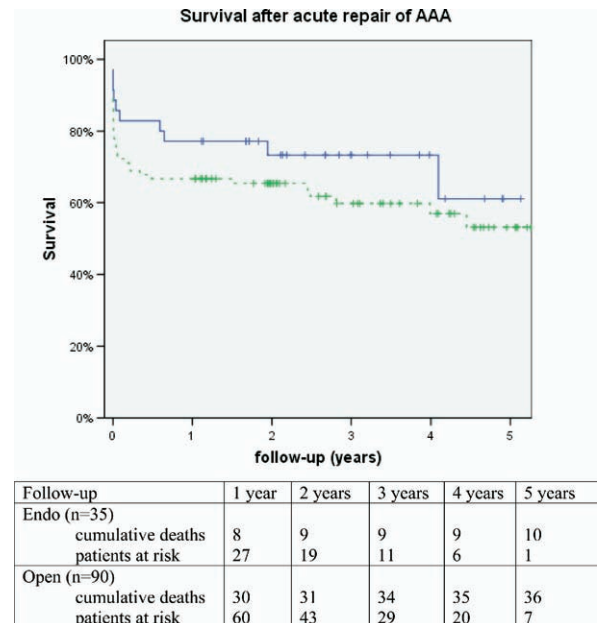


Fig 4. Kaplan-Meier survival curve for patients with ruptured abdominal aortic aneurysm treated with endovascular aneurysm repair (EVAR, solid line) and open repair (dotted line) ($P = .24$, SE $>10\%$ at 3 years for EVAR and 4 years for open repair).

13 patients operated on by other surgeons, with or without a consultant vascular surgeon): 28.9% (11 of 38) for surgeon I, 22.2% (6 of 27) for surgeon II, 31.8% (7 of 22) for surgeon III, and 20% (5 of 25) for surgeon IV (Kruskal-Wallis test, $P = .75$).

Complications. Three (8.3%) EVAR patients required reintervention, two for an abdominal compartment syndrome and one for an ischemic colon in conjunction with an abdominal compartment syndrome. Reintervention was required in 24 open patients (28.1%) for postoperative bleeding in 8, ischemic colon in 7, limb ischemia in 6, sepsis in 3, and abdominal fascia dehiscence in 1. The 30-day reintervention rate was lower with EVAR than with open repair (8.3% vs 28.1%, $P < .01$).

Follow-up. During the follow-up of 25 months (range, 1-64 months), 16 patients died. Fig 4 shows the

Table. Mortality of ruptured abdominal aortic aneurysm according to hemodynamic stability and treatment modality

<i>Procedure</i>	<i>Group I</i>	<i>Group II</i>	<i>Group III</i>	<i>Total</i>
Open, No. (%)	12/44 (27.3)	2/16 (12.5)	11/29 (37.9)	25/89 (28.1)
EVAR, No. (%)	3/29 (10.3)	1/6 (16.7)	1/1 (100)	5/36 (13.9)
Total, No. (%)	15/73 (20.5)	3/22 (13.6)	12/30 (40)	30/125 (24)

EVAR, Endovascular aneurysm repair.

survival curve according to treatment modality. There was no statistical difference in survival between EVAR and open repair ($P = .24$). Eleven patients died of probably unrelated causes (5 cardiac, 3 pulmonary, 1 ruptured type A dissection, 1 malignancy, 1 age), three of indeterminate aneurysm-related causes (2 unknown, 1 probable rupture of thoracic aneurysm), and two of aneurysm-related causes (1 due to sepsis after 2 months, 1 due to pneumonia after 2 months, both open repairs).¹⁶

Late reinterventions were performed in four of the 95 surviving patients. One EVAR patient presented with a painful AAA after 42 months due to disconnection of both graft limbs. This was immediately treated by endovascular means with bridging stent grafts.¹⁷ Three open-treated patients underwent four reinterventions. The first patient had two procedures, one at 5 months to re-establish bowel continuity and another at 24 months to correct an incisional hernia. The second patient had an incisional hernia repaired at 46 months. Finally, the third patient underwent coiling of an internal iliac aneurysm after 18 months.

DISCUSSION

This study evaluates the first 5 years of a strategy of offering EVAR and open repair to patients with a RAAA according to hemodynamic and anatomic criteria. Mortality rates both with open repair (28.1%) and EVAR (13.9%) compare well with the available literature.^{1,10,11} Overall mortality was 24%, which is remarkably low, especially if one considers that 93% of all admitted patients were treated. Basnyat et al¹⁸ reported that about 50% of all patients with a RAAA were refused treatment.

In our series, only 10 patients (7%) were not treated. Four patients were denied treatment on admission (2 died ≤ 1 hour) because of age and comorbidity. An additional six patients who were evaluated but not suitable for EVAR ultimately did not undergo open repair because two refused and four were determined to be totally unfit for open repair. The low mortality rates both in open repair and EVAR may have been influenced by the protocol requiring the presence of a senior vascular surgeon even before admission of the patient. Open repair after evaluation with CT scan adds anatomic information for the operating surgeon, which may improve outcome.

Hemodynamically unstable patients (group III) had a worse outcome compared with more stable patients on admission. These patients were immediately treated with open repair, but with a mortality rate of 37.9%, results are still in range with the current literature. Evaluation for EVAR by CT scan occurred in 77%. The main reason not to

evaluate patients was hemodynamic instability during the admission at the emergency department. During the study period, both the evaluation of patients for EVAR as the ratio of patients treated by EVAR increased (Fig 2). This is probably explained by a 24 hours a day, 7 days a week, multidisciplinary on-call system for RAAA, including a vascular surgeon, interventional radiologist, and radiology technicians, who are in the hospital at all times.

The availability of a 64-multi-slice CT scan in the emergency department is another important asset, and total time for CT scanning and evaluation of the images was < 30 minutes. Another possible explanation to allow for evaluation with a CT scan may be the strict fluid restriction protocol applied both by the ambulance services and our emergency department. Indeed, 57% of patients were stable (group I) at arrival, and only 25% were hemodynamically unstable (group III).

A comparison between EVAR and open repair seems inappropriate, because of an obvious bias created by anatomic selection criteria and hemodynamic stability on admission. Open repair was clearly used in more complex cases and unstable patients, which required more extensive dissection and even suprarenal clamping in 35%. This affects not only mortality rates but also time events such as operation time, blood transfusion requirement (eg, due to larger retroperitoneal hematoma), complication rates, and intensive care unit and hospital length of stay. To our surprise, survival curves were parallel, although the open repair patients presented with more complex aneurysms.

Although the option to treat patients with suitable RAAA by EVAR under local anesthesia presents with undeniable potential advantages, as shown in many cohort studies, scientific proof is lacking.²⁻⁹ A recently published nationwide survey in the United States concluded that EVAR is being increasingly used, with steadily decreasing mortality rates, but differences in patient disease, selection, or timing of intervention could not be appreciated from the data.¹⁹ This obviously adds to the question of the validity of the conclusions, in view of the same bias (easier anatomy and more stable patients). In our opinion, open repair and EVAR should be regarded as complementary techniques to improve outcome of patients with a RAAA.

Whether EVAR without CT scan is an option for patients who are unstable remains open. Some have suggested this approach, but scientific proof is lacking.¹³ Our results seem to indicate otherwise (Table). Group III had a mortality rate of 37.9%, and attempting EVAR in a few suitable cases with questionable outcome might impair the outcome of the remaining patients who in the end still need

open repair but with a considerable delay of treatment. Obviously, we have only limited experience with EVAR in unstable patients (group II and III).

The major limitation of this study is treatment selection. Comparing the two technical options remains biased, and only a randomized trial might provide the answer. Such a trial is currently ongoing, and results are expected later this year.²⁰

Another important limitation that may explain our good results is patient bias. Indeed, our tertiary referral center is regarded the first address for a patient with an RAAA, but we cannot account for those patients who were too unstable to be transported to us and were taken to a nearby regional hospital. Although some of these patients were later still referred to us, others may have died in surgery or on the way to the local hospital. Compared with other regions worldwide, distances are short in The Netherlands—rarely more than 1-hour transport time—even to our center, and ambulance services are well organized.²¹

Finally, although EVAR in elective patients has higher procedural costs than open repair, this seems not to be the case in acute EVAR. Indeed, a cost analysis on a subgroup of patients demonstrated a benefit in favor of EVAR in two studies, including our own patient population.^{22,23}

CONCLUSION

The capability of offering EVAR and open repair for RAAA according to hemodynamic and anatomic criteria seems to be associated with improved survival.

AUTHOR CONTRIBUTIONS

Conception and design: EV, MK, HG

Analysis and interpretation: EV, HG, IT, CZ, JV

Data collection: EV, MK, IT, CZ, JV, FB

Writing the article: EV, MK, HG

Critical revision of the article: EV, IT, CZ, JV

Final approval of the article: EV, MK, HG, IT, CZ, JV, FB

Statistical analysis: EV, HG, IT, CZ

Obtained funding: Not applicable

Overall responsibility: EV

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